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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,110	10/08/2003	Stephen James Field	0119/0027	4691

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EXAMINER	
MITCHELL, TEENA KAY	

ART UNIT	PAPER NUMBER
3771	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

C

Office Action Summary	**Application No.** 10/680,110	**Applicant(s)** FIELD, STEPHEN JAMES	
	Examiner Teena Mitchell	**Art Unit** 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2003*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-18* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☒ All b)☐ Some * c)☐ None of:
1.☒ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date *3/09/04*.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

While applicant has made a statement, the statement is incorrect. Applicant states, "...a duty to disclose information which is **material to the examination** of the application under 37 CFR 1.56 (a). The correct statement should be "...the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56..." the use of the wording "to the examination" is improper.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-13, and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipation by Russo (5,775,325).

Russo in a valve discloses a deformable member (22), said deformable member (22) having a fluid (Fig. 7) passage extending there through, and a normally-closed opening (Fig. 5) within said passage arranged such that it can be opened by external pressure applied to said deformable member (Fig. 7); and an external member (24, 25) displaceable on said deformable member between a first position in which said opening through said deformable member remains substantially closed and a second position in which said opening is opened.

Regarding claim 2, Russo discloses wherein said external member (24, 25) is arranged to remain in said first position until manual force is applied to displace it to the other position (Figs. 5, 7).

Regarding claim 3, Russo discloses wherein said deformable member is a collar (60) embracing said deformable member (22).

Regarding claim 5, Russo discloses wherein said first position is located to one side of said opening and said second position is substantially aligned with said opening (Figs. 5, 7).

Regarding claim 6, Russo discloses a rigid housing (at 20) externally of said deformable member (22) and wherein a part of said deformable member (24, 25) projects outwardly through an opening in said rigid housing for engagement by said external member.

Regarding claim 7, Russo discloses wherein said deformable member (22) has a part with an inclined surface arranged for engagement by said external member (Figs. 1, 4-7, 8, 10, 11).

Regarding claim 8, Russo discloses wherein said housing has two openings (Figs. 1, 4-7) diametrically opposite one another, wherein said deformable member has two pads (24, 25) projecting outwardly through respective one of said openings, and wherein said pads each have an inclined surface shaped for engagement by said external member such that placement of said external member causes said pads (24, 25) to be pushed towards one another thereby opening said opening (Figs. 1, 4-7, 8, 10, 11).

Regarding claim 9, Russo discloses wherein said normally-closed opening is a slit (28) extending diametrically of said passage (Figs. 5, 7, 8-12).

Regarding claim 10, Russo discloses wherein said deformable member (22) is generally tubular and has a transverse web (29, 30) extending across its diameter and formed integrally with said deformable member, and wherein said slit (28) is provided in said web (Figs. 8-12).

Regarding claim 11, Russo discloses a substantially rigid reinforcement member (58, 59) extending parallel to said slit on opposite sides such that when force is applied externally along said slit reinforcement member is bowed outwardly to open aid slit (Figs. 8, 11).

Regarding claim 12, Russo discloses a deformable member (22) having a fluid passage extending there through; an internal seal (28) of a deformable material defining a slit (28) extending transversely of said fluid passage (Figs. 5, 7); and a substantially rigid reinforcement member (58, 59; Figs. 8, 10, 11) extending parallel to said slit on opposite sides such that when a force is applied externally along said slit said reinforcement member is bowed outwardly to open said slit (Figs. 8, 10, 11).

Regarding claim 13, Russo discloses a tubular deformable member (22), said deformable member having a fluid passage extending there through (Figs. 5, 7), a closure member (Figs. 8, 10, 11) extending across said fluid passage and having a normally-closed slit (28) arranged such that said slit can be opened by external pressure applied to said tubular member (22); and external collar (60) slidable along said tubular member between a first position in which said slit (28) remains substantially closed and a second position in which said slit (28) is opened.

Regarding claim 15, Russo discloses a closed suction catheter assembly comprising a suction catheter (44) and a valve (22) said valve comprising a deformable member (22), said deformable member (22) having a fluid (Fig. 7) passage extending there through, and a normally-closed opening (Fig. 5) within said passage arranged such that it can be opened by external pressure applied to said deformable member (Fig. 7); and an external member (24, 25) displaceable on said deformable member between a first position in which said opening through said deformable member remains substantially closed and a second position in which said opening is opened.

Regarding claim 16, Russo discloses a cleaning chamber (34) located towards a patient end of said assembly, wherein said valve (22) is located towards a patient said of said cleaning chamber, and wherein said valve is openable to allow extension of said suction catheter and is closable substantially to isolate said cleaning chamber from the patient and enable cleaning of said catheter (Figs. 1, 4-7)

Regarding claim 17, Russo discloses wherein said valve is located towards a machine end of said assembly (Figs. 1, 4-7) and is connected at a machine end of said suction catheter (44) so as to enable or prevent suctioning along said catheter.

Regarding claim 18, Russo discloses a closed suction catheter assembly (Figs. 1, 4-7) comprising a suction catheter (44), a machine end fitting (at 53) including a suction control valve (not shown at 53) arranged to control suction applied to said catheter (44), a patient end fitting (at 48) having a sliding seal (at 42) through which said suction catheter can be advanced and retracted, and a flexible envelope (31) extending between said fittings, wherein said patient end fitting includes a cleaning chamber (34) on a patient side of said sliding seal (42), said cleaning chamber including an inlet (at 35) for cleaning fluid and a valve (at 22), and wherein said valve includes a tubular deformable member (Figs. 1, 4-7; 22), said deformable member having a fluid passage extending there through, a closure member (at 28) extending across said fluid passage and having a slit (Figs. 2, 8, 10, 11) normally closed to isolate said cleaning chamber (34, Fig. 5) from the patient; and an external collar (60) slidable along said tubular member between a first position in which said slit (28) remains substantially closed and a second position in which said collar applies pressure to said tubular member to open said slit (Figs. 7, 8, 11) and to allow the catheter (44) to be advanced from said cleaning chamber.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. **Determining the scope and contents of the prior art.**
2. **Ascertaining the differences between the prior art and the claims at issue.**
3. **Resolving the level of ordinary skill in the pertinent art.**
4. **Considering objective evidence present in the application indicating obviousness or nonobviousness.**

Claims 4, 14, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russo (5,775,325).

Regarding claim 4, Russo discloses the claimed invention except for the external member being displaced by sliding lengthwise of said passage. At the time the external member being displaced by sliding lengthwise of said passage invention was made, it would have been an obvious matter of design consideration to a person of ordinary skill in the art to have the external member being displaced by sliding lengthwise of said passage because applicant has not disclosed that the external member being displaced by sliding lengthwise of said passage provides an advantage or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well the external member movable in any position because the valve member would still be able to close to allow no passage of fluids when the valve is closed. Therefore, it would have been an obvious matter of design consideration to modify the external member of Russo to obtain the invention as specified in claim 4.

Regarding claim 14, note rejections of claims 8 and 4 above.

Regarding claim 18, Russo discloses a closed suction catheter assembly (Figs. 1, 4-7) comprising a suction catheter (44), a machine end fitting (at 53) including a suction control valve (not shown at 53) arranged to control suction applied to said catheter (44), a patient end fitting (at 48) having a sliding seal (at 42) through which said suction catheter can be advanced and retracted, and a flexible envelope (31) extending between said fittings, wherein said patient end fitting includes a cleaning chamber (34) on a patient side of said sliding seal (42), said cleaning chamber including an inlet (at 35) for cleaning fluid and a valve (at 22), and wherein said valve includes a tubular deformable member (Figs. 1, 4-7; 22), said deformable member having a fluid passage extending there through, a closure member (at 28) extending across said fluid passage and having a slit (Figs. 2, 8, 10, 11) normally closed to isolate said cleaning chamber (34, Fig. 5) from the patient. With respect to the external collar slidable along said tubular member between a first position in which said slit (28) remains substantially closed and a second position in which said collar applies pressure to said tubular member to open said slit (Figs. 7, 8, 11) and to allow the catheter (44) to be advanced from said cleaning chamber, not rejection of claim 4 above.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show valve and suction devices: 6,923,184; 4,960,412; 2006/0202146; 2003/0066980; 5,269,771.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teena Mitchell
Teena Mitchell
Primary Examiner
Art Unit 3771
June 1, 2007

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